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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): SANDERS et al.

Patent No.: 7,033,595 B1

Issued: April 25, 2006 Docket No.: 290.00490101

Title: PSEUDOTYPED RETROVIRUSES AND STABLE CELL LINES FOR THEIR PRODUCTION

Certificate

DEC 2 0 2007

of Correction

Attention Decisions and Certificate of Correction Branch
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

We are transmitting the following documents along with this Transmittal Sheet (which is submitted in triplicate):

X **Small entity status is entitled to be asserted in the above-identified application.**

X An itemized return postcard.

__ A Petition for Extension of Time for __ month(s). Please charge Deposit Account No. _____ in the amount of $__ for the required fee.

__ An Information Disclosure Statement (__ pgs); copies of ___ applications; 1449 forms (__ pgs); and copies of ___ documents cited on the 1449 forms.

__ A request for continued examination (RCE). Please charge Deposit Account No. _____ in the amount of $ ___, for the required filing fee.

__ An Appeal Brief. Please charge Deposit Account No. _____ in the amount of $__, for the required Appeal Brief filing fee.

__ A check in the amount of $__, representing ___.

__ A certified copy of a __ application, Serial No. _, filed _____, the right of priority of which is claimed under 35 U.S.C. §119.

X Other: Request for Reconsideration of Certificate of Correction (2 pgs); Exhibit A - Copy of Notice of Allowance mailed on October 14, 2005 (4 pgs); Exhibit B - Copy of Amendment and Response filed on November 17, 2004 (23 pgs); Certificate of Correction (in duplicate) (1 pg).

__ Amendment ___ No Additional fee is required. ___ The fee has been calculated as shown:

Fee Calculation for Claims Pending After Amendment					
	Pending Claims after Amendment (1)	Claims Paid for Earlier (2)	Number of Additional Claims (1-2)	Cost per Additional Claim	Additional Fees Required
Total Claims				x $25 =	
Independent Claims				x $105 =	
One or More New Multiple Dependent Claims Presented? If Yes, Add $185 Here→					
Total Additional Claim Fees Required					

Please consider this a PETITION FOR EXTENSION OF TIME for a sufficient number of months to enter these papers and please charge any additional fees or credit overpayment to Deposit Account No. 13-4895. Triplicate copies of this sheet are enclosed.

CERTIFICATE UNDER 37 C.F.R. §1.8: The undersigned hereby certifies that this Transmittal Letter and the paper(s), as described hereinabove, are being deposited in the United States Postal Service, as first class mail, in an envelope addressed to: **Attention Decisions and Certificate of Correction Branch,** Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 13 day of December, 2007.

MUETING, RAASCH & GEBHARDT, P.A.
Customer Number: 26813

By: Nancy A. Johnson
Name: Nancy A. Johnson
Reg. No.: 47,266
Direct Dial: 612-305-4723
Facsimile: 612-305-1228

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): SANDERS et al.

Patent No.: 7,033,595 B1

Issued: April 25, 2006 Docket No.: 290.00490101

Title: PSEUDOTYPED RETROVIRUSES AND STABLE CELL LINES FOR THEIR PRODUCTION

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Name: Nancy A. Johnson
Reg. No.: 47,266
Direct Dial: 612-305-4723
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(SMALL ENTITY TRANSMITTAL UNDER RULE 1.8)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): SANDERS et al.

Patent No.: 7,033,595 B1

Issued: April 25, 2006 Docket No.: 290.00490101

Title: PSEUDOTYPED RETROVIRUSES AND STABLE CELL LINES FOR THEIR PRODUCTION

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P.O. Box 1450
Alexandria, VA 22313-1450

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__ An Appeal Brief. Please charge Deposit Account No. _____ in the amount of $___, for the required Appeal Brief filing fee.

__ A check in the amount of $_, representing ___.

__ A certified copy of a _ application, Serial No. _, filed _____, the right of priority of which is claimed under 35 U.S.C. §119.

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One or More New Multiple Dependent Claims Presented? If Yes, Add $185 Here→					
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Name: Nancy A. Johnson
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(SMALL ENTITY TRANSMITTAL UNDER RULE 1.8)

PATENT
Docket No. 290.00490101

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): SANDERS et al.

Patent No.: 7,033,595 B1

Issued: April 25, 2006

For: PSEUDOTYPED RETROVIRUSES AND STABLE CELL LINES FOR THEIR PRODUCTION

REQUEST FOR RECONSIDERATION OF CERTIFICATE OF CORRECTION

Attention Decisions and Certificate of Correction Branch
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Applicants request reconsideration of the U.S. Patent and Trademark's denial in a communication mailed August 24, 2007, of Applicant's request filed June 6, 2006, for the issuance of a certificate of correction under the provisions of C.F.R. §1.322 canceling issued claims 11 and 16 in the above-identified patent. In the communication mailed August 24, 2007, the U.S. Patent and Trademark Office asserted that claims issued 11 and 16 were not canceled in prosecution. Applicants respectfully submit that this assertion is incorrect.

Applicants provide herewith a copy of the Notice of Allowability mailed October 14, 2005 (Exhibit A) indicating that, with allowance, original claim 24 was renumbered as claim claim 11 and original claim 29 was renumbered as claim 16 (see item 2, Notice of Allowability mailed October 14, 2005 (Exhibit A)). Thus, issued claims 11 and 16 correspond to original claims 24 and 29 during the prosecution of this patent.

Applicants provide herewith a copy of the Amendment and Response filed November 17, 2004 (Exhibit B), in response to a non-final Office Action mailed August 26, 2004, instructing that original claim 24 (issued claim 11) and original claim 29 (issued claim 16) be canceled. Specifically, see the claim identifier "canceled" associated with each of original claims 24 and 29 (pages 6 and 7 of Amendment and Response filed November 17, 2004 (Exhibit A)) and the statement "claims 24 and 29 having been canceled" (page 15 of Amendment and Response filed November 17, 2004 (Exhibit A)).

Applicants respectfully submit that issued claim 11 (original claim 24) and issued claim 16 (original claim 29) were canceled during prosecution. Applicants request a Certificate of Correction be issued, indicating that the proper status of issued claims 11 and 16 is canceled. Two copies of the text noting this correction are enclosed. Since none of the errors listed are due to Applicants' mistake, no fee is necessary for the Certificate. The corrections in the proposed Certificate of Correction do not involve such changes in the patent as would constitute new matter or would require reexamination.

Please mail the printed Certificate of Correction to the undersigned attorney.

CERTIFICATE UNDER 37 C.F.R. 1.8:

The undersigned hereby certifies that this paper is being deposited in the United States Postal Service, as first class mail, in an envelope addressed to: **Attention Decisions and Certificate of Corrections Branch**, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 13th day of December, 2007.

Signature: R Englund
Name: Rachel Englund

December 13, 2007
Date

Respectfully submitted
By
Mueting, Raasch & Gebhardt, P.A.
P.O. Box 581415
Minneapolis, MN 55458-1415
Phone: (612) 305-1220
Facsimile: (612) 305-1228
Customer Number 26813

By: Nancy A. Johnson
Nancy A. Johnson
Reg. No. 47,266
Direct Dial (612) 305-4723

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Printer's Trim Line

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO.: 7,033,595 B1
DATED: April 25, 2006
INVENTOR(S): Sanders et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Please cancel claim 11.

Please cancel claim 16.

MAILING ADDRESS OF SENDER:

MUETING, RAASCH & GEBHARDT, P.A.
P.O. BOX 581415
MINNEAPOLIS, MINNESOTA 55401
Customer Number 26813

PATENT NO. 7,033,595 B1

No. of add'l copies

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UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO.: 7,033,595 B1
DATED: April 25, 2006
INVENTOR(S): Sanders et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Please cancel claim 11.

Please cancel claim 16.

MAILING ADDRESS OF SENDER:

MUETING, RAASCH & GEBHARDT, P.A.
P.O. BOX 581415
MINNEAPOLIS, MINNESOTA 55401
Customer Number 26813

PATENT NO. 7,033,595 B1

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UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

NOTICE OF ALLOWANCE AND FEE(S) DUE

26813 7590 10/14/2005

MUETING, RAASCH & GEBHARDT, P.A.
P.O. BOX 581415
MINNEAPOLIS, MN 55458

EXAMINER
PARKIN, JEFFREY S

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 10/14/2005

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/762,224	07/30/2001	David A. Sanders	7024-497PUR115	2859

TITLE OF INVENTION: PSEUDOTYPED RETROVIRUSES AND STABLE CELL LINES FOR THEIR PRODUCTION

APPLN. TYPE	SMALL ENTITY	ISSUE FEE	PUBLICATION FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	$700	$0	$700	01/17/2006

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE REFLECTS A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE APPLIED IN THIS APPLICATION. THE PTOL-85B (OR AN EQUIVALENT) MUST BE RETURNED WITHIN THIS PERIOD EVEN IF NO FEE IS DUE OR THE APPLICATION WILL BE REGARDED AS ABANDONED.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL should be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). Even if the fee(s) have already been paid, Part B - Fee(s) Transmittal should be completed and returned. If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PTOL-85 (Rev. 07/05) Approved for use through 04/30/2007.

EXHIBIT A

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/762,224	07/30/2001	David A. Sanders	7024-497PUR115	2859

26813 7590 10/14/2005

MUETING, RAASCH & GEBHARDT, P.A.
P.O. BOX 581415
MINNEAPOLIS, MN 55458

EXAMINER	
PARKIN, JEFFREY S	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 10/14/2005

Determination of Patent Term Extension under 35 U.S.C. 154 (b)
(application filed after June 7, 1995 but prior to May 29, 2000)

The Patent Term Extension is 0 day(s). Any patent to issue from the above-identified application will include an indication of the 0 day extension on the front page.

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Extension is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571) 272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at (703) 305-8283.

PTOL-85 (Rev. 07/05) Approved for use through 04/30/2007.

Notice of Allowability

Application No.	Applicant(s)	
09/762,224	SANDERS ET AL.	
Examiner	**Art Unit**	
Jeffrey S. Parkin, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *the amendment filed 25 May, 2005*.

2. ☒ The allowed claim(s) is/are *original claims 1-4, 8, 9, 11, 12, 19, 20, 24-29, 33, 34, 40, 53, 56-58, renumbered 1-23, respectively*.

3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
7. ☐ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

Jeffrey S. Parkin, Ph.D.
Primary Examiner
Art Unit: 1648

EXHIBIT B

PATENT
Docket No. 290.00490101

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s):	Sanders et al.	)	Group Art Unit: 1648
Serial No.:	09/762,224	)	Examiner: Jeffrey S. PARKIN
Confirmation No.:	2859	)	
Filed:	30 July 2001	)	

For: PSEUDOTYPED RETROVIRUSES AND STABLE CELL LINES FOR THEIR PRODUCTION

FACSIMILE TRANSMISSION TO THE PTO

Mail Stop Amendment
Commissioner for Patents
Attn: Examiner Parkin
P.O. Box 1450
Alexandria, VA 22313-1450

FAX NUMBER: **(703) 872-9306**
Total Pages (including cover page): 21
Time: 11:50 A.M (Central Time)
(Transmission must be complete by midnight eastern time.)

The following papers are being transmitted to the Patent and Trademark Office by facsimile transmission: Amendment and Response (20 pages)

X **Small Entity Status is entitled to be asserted in the above-identified application.**

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Mueting, Raasch & Gebhardt, P.A.
Customer Number: 26813

Nov 17, 2004
Date

By: V.A. Sandberg
Victoria A. Sandberg
Reg. No. 41,287
Direct Dial (612)305-1226

CERTIFICATE UNDER 37 C.F.R. §1.8: The undersigned hereby certifies that this Facsimile Cover Sheet and the paper(s), as described hereinabove, are being transmitted by facsimile in accordance with 37 CFR §1.6(d) to the Patent and Trademark Office addressed to the Mail Stop Amendment, Commissioner for Patents, Attn: Examiner Parkin, P.O. Box 1450, Alexandria, VA 22313-1450, on this 17 day of November, 2004, at 11:50 A.M. (Central Time).

11-17-04
Date

Signature: Sandy Truehart
Name: Sandy Truehart

If you do not receive all pages, please contact us at (612)305-1220 (ph) or (612)305-1228 (fax).

PATENT
Docket No. 290.00490101

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s):	Sanders et al.	Group Art Unit:	1648
Serial No.:	09/762,224	Examiner:	Jeffrey S. PARKIN
Confirmation No.:	2859		
Filed:	30 July 2001		

For: PSEUDOTYPED RETROVIRUSES AND STABLE CELL LINES FOR THEIR PRODUCTION

AMENDMENT AND RESPONSE

Commissioner for Patents
Mail Stop Amendment
Attn: Examiner Parkin
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

In response to the Office Action mailed 26 August 2004, please amend the above-identified application as follows:

Amendments to the Specification begin on the page entitled "Amendments to the Specification."

Amendments to the Claims are reflected in the listing of claims which begins on the page entitled "Amendments to the Claims."

Remarks begin on the page entitled "Remarks."

Amendments to the Specification

Please replace the paragraph beginning at page 1, line 6, with the following amended paragraph.

This present application is a National Stage entry of International Application No. PCT/US99/17702, filed August 4, 1999, which claims the benefit of U.S. Patent Provisional Patent Application Serial No. 60/095,242, filed August 4, 1998, and U.S. Provisional Patent Application Serial No. 60/112,405, filed December 15, 1998, which are both hereby incorporated by reference in their entirety.

Amendments to the Claims

This listing of claims replaces all prior versions, and listings, of claims in the above-identified application:

Listing of Claims

1. (Currently amended) A pseudotyped-retrovirus-producing eukaryotic cell, comprising[:] a eukaryotic cell including nucleotide sequences operatively encoding components of a pseudotyped retrovirus, said nucleotide sequences comprising:

(a) a first nucleotide sequence operably encoding a retroviral Gag polypeptide;

(b) a second nucleotide sequence operably encoding a retroviral Pro polypeptide;

(c) a third nucleotide sequence operably encoding a retroviral Pol polypeptide; and

(d) a fourth nucleotide sequence operably encoding at least two different viral glycoproteins.

2. (Previously presented) The cell of claim 1, wherein said cell further comprises a fifth nucleotide sequence having a 5′ and a 3′ end, said fifth nucleotide sequence encoding a selected protein, said fifth nucleotide sequence operably linked at said 5′ end to a first retroviral long terminal repeat sequence and operably linked at said 3′ end to a second retroviral long terminal repeat sequence.

3. (Previously presented) The cell of claim 2, wherein said selected protein is a marker.

4. (Original) The cell of claim 3, wherein said marker is a fluorescent protein.

5. (Original) The cell of claim 1, wherein said two different viral glycoproteins are togaviral glycoproteins.

6. (Original) The cell of claim 5, wherein said togaviral glycoproteins are alphaviral glycoproteins.

7. (Original) The cell of claim 6, wherein said alphaviral glycoprotein is a Ross River alphaviral glycoprotein.

8. (Original) The cell of claim 1, wherein said eukaryotic cell is a mammalian cell.

9. (Original) The cell of claim 8, whererin said mammalian cell is a human cell.

10. (Original) The cell of claim 1, wherein said retroviral Gag, Pol and Pro polypeptides are comprised of Moloney murine leukemia Gag, Pro and Pol polypeptides.

11. (Original) The cell of claim 1, wherein said cell produces a pseudotyped retrovirus having a lipid bilayer, said viral glycoproteins disposed in said lipid bilayer.

12. (Original) The cell of claim 1, wherein said first, second, third and fourth nucleotide sequences are chromosomally-integrated.

13. (Withdrawn) A eukaryotic cell, comprising:

(a) a first nucleotide sequence encoding a retroviral Gag polypeptide;

(b) a second nucleotide sequence encoding a retroviral Pro

polypeptide;

(c) a third nucleotide sequence encoding a retroviral Pol polypeptide; and

(d) a fourth nucleotide sequence encoding a filoviral glycoprotein, said first, second, third and fourth nucleotide sequences being chromosomally-integrated, said cell stably producing pseudotyped retroviruses.

14. (Withdrawn) The cell of claim 13, wherein said cell further comprises a fifth nucleotide sequence having a 5′ end and a 3′ end, said fifth nucleotide sequence encoding a desired protein, said fifth nucleotide sequence operably linked at said 5′ end to a first retroviral long terminal repeat sequence and operably linked at said 3′ end to a second retroviral long terminal repeat sequence.

15. (Withdrawn) The cell of claim 13, wherein said filoviral glycoprotein is selected from the group consisting of Marburg virus glycoprotein and Ebola virus glycoprotein.

16. (Withdrawn) The cell of claim 13, wherein said retroviral Gag, Pro and Pol polypeptides are comprised of Moloney murine leukemia virus Gag, Pro and Pol polypeptides.

17. (Withdrawn) The cell of claim 13, wherein said cell produces pseudotyped retrovirus at a titer of at least about 4.5×10^4 transforming units/ml of supernatant.

18. (Withdrawn) A eukaryotic cell, comprising:

(a) a first nucleotide sequence encoding a retroviral Gag polypeptide;

(b) a second nucleotide sequence encoding a retroviral Pro polypeptide;

(c) a third nucleotide sequence encoding a retroviral Pol

polypeptide; and

(d) a fourth nucleotide sequence encoding a Marburg virus glycoprotein.

19. (Currently amended) A method of ~~forming~~ modifying a eukaryotic cell to prepare a pseudotyped-retrovirus-producing eukaryotic cell ~~for producing pseudotyped retroviruses~~, said method comprising:

transfecting a eukaryotic cell with a first nucleotide sequence operably encoding a retroviral Gag polypeptide, a second nucleotide sequence operably encoding a retroviral Pro polypeptide, a third nucleotide sequence operably encoding a retroviral Pol polypeptide and a fourth nucleotide sequence operably encoding at least two different viral glycoproteins.

20. (Original) The method of claim 19, wherein said first, second and third nucleotide sequences are operably linked to a promoter sequence.

21. (Original) The method of claim 19, wherein said viral glycoproteins are togaviral glycoproteins.

22. (Original) The method of claim 21, wherein said togaviral glycoproteins are alphaviral glycoproteins.

23. (Original) The method of claim 22, wherein said alphaviral glycoproteins are Ross River alphaviral glycoproteins.

24. (Canceled) The method of claim 19, wherein said first, second, third and fourth nucleotide sequences are chromosomally-integrated.

25. (Previously presented) The method of claim 19, wherein said cell further comprises a

fifth nucleotide sequence having a 5′ end and a 3′ end, said fifth nucleotide sequence encoding a selected protein, said fifth nucleotide sequence operably linked at said 5′end to a first retroviral long terminal repeat sequence and operably linked at said 3′ end to a second retroviral long terminal repeat sequence.

26. (Currently amended) A method of ~~forming~~ modifying a eukaryotic cell to prepare a pseudotyped-retrovirus-producing eukaryotic cell ~~for producing pseudotyped retroviruses~~, said method comprising:

(a) transfecting a eukaryotic cell with a vector including a first nucleotide sequence encoding a retroviral Gag polypeptide, a second nucleotide sequence encoding a retroviral Pro polypeptide and a third nucleotide sequence encoding a retroviral Pol polypeptide, said first, second and third nucleotide sequences operably linked to a first promoter sequence; and

(b) transfecting said cell with a fourth nucleotide sequence encoding at least two viral glycoproteins, said fourth nucleotide sequence operably linked to a second promoter sequence.

27. (Previously presented) The method of claim 26, said method further comprising transfecting said cell with a vector including a fifth nucleotide sequence having a 5′ and a 3′ end, said fifth nucleotide sequence encoding a selected protein, said fifth nucleotide sequence operably linked at said 5′ end to a first retroviral long terminal repeat sequence and operably linked at said 3′ end to a second retroviral long terminal repeat sequence.

28. (Previously presented) The method of claim 26, wherein said selected protein is a marker.

29. (Canceled) The method of claim 26, wherein said first, second, third and fourth nucleotide sequences are chromosomally-integrated.

30. (Withdrawn) A method of forming a eukaryotic cell for producing pseudotyped retroviruses, said method comprising:
(a) transfecting a eukaryotic cell with a first nucleotide sequence encoding a retroviral Gag polypeptide, a second nucleotide sequence encoding a retroviral Pro polypeptide, a third nucleotide sequence encoding a retroviral Pol polypeptide and a fourth nucleotide sequence encoding a filoviral glycoprotein, said first, second, third and fourth nucleotide sequences being chromosomally-integrated, said cell stably producing pseudotyped retroviruses.

31. (Withdrawn) The method of claim 30, wherein said filoviral glycoprotein is selected from the group consisting of Ebola virus glycoprotein and Marburg virus glycoprotein.

32. (Withdrawn) A method of forming a eukaryotic cell for producing pseudotyped retroviruses, said method comprising:

transfecting a eukaryotic cell with a first nucleotide sequence encoding a retroviral Gag polypeptide, a second nucleotide sequence encoding a retroviral Pro polypeptide, a third nucleotide sequence encoding a retroviral Pol polypeptide and a fourth nucleotide sequence encoding a Marburg virus glycoprotein.

33. (Original) A pseudotyped retrovirus, comprising:

(a) a retroviral capsid;

(b) a lipid bilayer; said lipid bilayer surrounding said retroviral capsid; and

(c) at least two different viral glycoproteins disposed in said lipid bilayer.

34. (Previously presented) The retrovirus of claim 33, said retrovirus further comprising a nucleotide sequence encoding a selected protein, said nucleotide sequence enclosed within said retroviral capsid.

35. (Original) The retrovirus of claim 33, wherein said viral glycoproteins are togaviral glycoproteins.

36. (Original) The retrovirus of claim 35, wherein said togaviral glycoproteins are alphaviral glycoproteins.

37. (Original) The retrovirus of claim 36, wherein said alphaviral glycoproteins are Ross River alphaviral glycoproteins.

38. (Original) The retrovirus of claim 33, wherein said retroviral capsid is comprised of a Moloney murine leukemia virus capsid.

39. (Withdrawn) A pseudotyped retrovirus, comprising:

(a) a retroviral capsid;

(b) a lipid bilayer; said lipid bilayer surrounding said retroviral capsid; and

(c) a Marburg virus glycoprotein disposed in said lipid bilayer.

40. (Currently amended) A method of introducing a selected nucleotide sequence into a cell~~, said method~~ comprising[:] transducing a cell ~~permissive for entry of a virus having at least two different viral glycoproteins in its lipid bilayer~~ with a pseudotyped retrovirus, said pseudotyped retrovirus comprising:

a selected nucleotide sequence;

a retroviral capsid;

a lipid bilayer surrounding said retroviral capsid; and

at least two different viral glycoproteins disposed in said lipid bilayer;

~~having a retroviral capsid;~~

~~a lipid bilayer; said lipid bilayer surrounding said retroviral capsid;~~

~~at least two different viral glycoproteins disposed in said lipid bilayer; and~~

~~a selected ribonucleotide sequence~~.

wherein said cell is permissive for entry of a pseudotyped retrovirus having at least two different viral glycoproteins in its lipid bilayer.

41. (Original) The method of claim 40, wherein said retroviral capsid is a Moloney murine leukemia virus capsid.

42. (Original) The method of claim 40, wherein said virus having at least two different glycoproteins in its lipid bilayer is a togavirus, and said at least two different viral glycoproteins are togaviral glycoproteins.

43. (Original) The method of claim 42, wherein said togavirus is an alphavirus and said togaviral glycoproteins are alphaviral glycoproteins.

44. (Withdrawn) A method of introducing a nucleotide sequence into a cell, said method comprising:

transducing a cell permissive for Marburg virus entry with a pseudotyped retrovirus having

a retroviral capsid;

a lipid bilayer; said lipid bilayer surrounding said retroviral capsid;

a Marburg virus glycoprotein disposed in said lipid bilayer; and

a desired ribonucleotide sequence.

45. (Withdrawn) A method of screening agents effective in blocking viral entry into a cell, said method comprising:

(a) treating a pseudotyped retrovirus with said agent, said pseudotyped retrovirus having a retroviral capsid;

a lipid bilayer, said lipid bilayer surrounding said retroviral capsid;

at least two different viral glycoproteins disposed in said lipid bilayer; and

a nucleotide sequence encoding a desired marker, said nucleotide sequence enclosed within said retroviral capsid;

(b) treating a cell permissive for entry of a virus having at least two different viral glycoproteins disposed in its lipid bilayer with said treated pseudotyped retrovirus; and

(c) identifying eukaryotic cells having the desired marker.

46. (Withdrawn) The method of claim 45, wherein said virus having at least two different viral glycoproteins disposed in its lipid bilayer is a togavirus and said two different viral glycoproteins are togaviral glycoproteins.

47. (Withdrawn) The method of claim 46, wherein said togavirus is an alphavirus and said togaviral glycoproteins are alphaviral glycoproteins.

48. (Withdrawn) The method of claim 45, wherein said agent is an immunological agent.

49. (Withdrawn) The method of claim 45, wherein said agent is a pharmacological agent.

50. (Withdrawn) A method of screening agents effective in blocking Marburg virus entry into a cell, said method comprising:

(a) treating a pseudotyped retrovirus with said agent, said pseudotyped retrovirus having a retroviral capsid;

a lipid bilayer, said lipid bilayer surrounding said retroviral capsid;

a Marburg virus glycoprotein disposed in said lipid bilayer; and

a nucleotide sequence encoding a desired marker, said nucleotide sequence enclosed within said retroviral capsid;

(b) treating a cell permissive for Marburg virus entry with said treated pseudotyped retrovirus; and

(c) identifying eukaryotic cells having the desired marker.

51. (Withdrawn) A method of screening agents effective in blocking viral entry into a cell, said method comprising:

(a) treating a cell permissive for entry of a virus having at least two different viral glycoproteins in its lipid bilayer with said agent;

(b) contacting said treated cell with a pseudotyped retrovirus having a retroviral capsid;

a lipid bilayer, said lipid bilayer surrounding said retroviral capsid;

at least two different viral glycoproteins disposed in said lipid bilayer;

a nucleotide sequence encoding a desired marker, said nucleotide sequence enclosed within said retroviral capsid; and

(c) identifying eukaryotic cells having the desired marker.

52. (Withdrawn) A method of screening agents effective in blocking viral entry into a cell, said method comprising:

(a) treating a cell permissive for entry of a Marburg virus with said agent;

(b) contacting said treated cell with a pseudotyped retrovirus having a retroviral capsid;

a lipid bilayer, said lipid bilayer surrounding said retroviral capsid;

a Marburg virus glycoprotein disposed in said lipid bilayer;

a nucleotide sequence encoding a desired marker, said nucleotide sequence enclosed within said retroviral capsid; and

(c) identifying eukaryotic cells having the desired marker.

53. (Currently amended) A kit for ~~forming a pseudotyped retrovirus~~ modifying a eukaryotic cell to prepare a pseudotyped-retrovirus-producing eukaryotic cell, said kit comprising:

(a) a first nucleotide sequence operably encoding a retroviral Gag polypeptide;

(b) a second nucleotide sequence operably encoding a retroviral Pro polypeptide;

(c) a third nucleotide sequence operably encoding a retroviral Pol polypeptide; and

(d) a fourth nucleotide sequence operably encoding at least two different viral glycoproteins; and

(e) means for transfecting a eukaryotic cell with said first, second, third, and fourth nucleotide sequences.

54. (Withdrawn) The method of claim 52, wherein said viral glycoproteins are togaviral glycoproteins.

55. (Withdrawn) A kit for forming a pseudotyped retrovirus, said kit comprising:

(a) a first nucleotide sequence encoding a retroviral Gag polypeptide;

(b) a second nucleotide sequence encoding a retroviral Pro polypeptide;

(c) a third nucleotide sequence encoding a retroviral Pol polypeptide; and

(d) a fourth nucleotide sequence encoding a Marburg virus glycoprotein.

56. (New) The method of claim 19, wherein the first, second, third, and fourth nucleotide sequences are provided on plasmid vectors.

57. (New) The method of claim 56, wherein the first, second, and third nucleotide sequences are contiguous on a single plasmid vector.

58. (New) The method of claim 57, wherein the fourth nucleotide sequence is on a different plasmid vector.

Remarks

The Office Action mailed 26 August 2004 has been received and reviewed.

The specification has been amended to clarify the benefit claim under 35 U.S.C. §119(e).

Claims 1, 19, 26, 40, and 53 having been amended, claims 56-58 having been added, and claims 24 and 29 having been canceled, the pending claims are claims 1-12, 19-23, 25-28, 33-38, 53, and 56-58. Support for the claim amendments is found throughout the specification.

Reconsideration and withdrawal of the rejections are respectfully requested.

The 35 U.S.C. §112, Second Paragraph, Rejection

The Examiner rejected claims 1-12, 19-29, 33-38, 40-43 and 53 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. This rejection is respectfully traversed.

A patent claim is sufficiently definite to satisfy 35 U.S.C. § 112, second paragraph, if one skilled in the art would understand the bounds of the claim when read in light of the specification. Exxon Research v. United States, 60 USPQ2d 1272 (Fed. Cir. 2001) (citing Miles Labs., Inc. v. Shandon, Inc., 27 USPQ2d 1123, 1126 (Fed. Cir. 1993). The Examiner asserts that claims 1-12, 19-29, 40-43, and 53 fail to satisfy 35 U.S.C. § 112, second paragraph, because they do not provide sufficient structural and functional limitations to enable the skilled artisan to ascertain the metes and bounds of the claimed invention, as well as failing to provide a functional nexus for the four nucleotide sequences.

Applicants have amended claims 1, 19, 26, 40, and 53 to clarify the functional nexus between the structural and functional limitations of the claims. In particular, the claims have been amended to be directed to pseudotyped-retrovirus-producing eukaryotic cells, or related aspects of the invention. Pseudotyped retroviruses are described in the specification as retroviruses provided with different envelope glycoproteins to expand the host range of the

retrovirus (see page 2, lines 4-12); this function is clear from recitation of the term "pseudotyped" in the claims. Structures that form the pseudotyped retrovirus in the context of a eukaryotic cell include the proteins encoded by the retroviral nucleotide sequences (namely, Gag, Pro, and Pol), which are distinctive for retrovirus formation, and sequences that form the viral glycoproteins, providing the "pseudotyped" aspect of the retrovirus, expanding or altering host range. These structures are recited in the claims. A functional nexus between the presence of these nucleotide sequence structures and the altered or expanded host range of a pseudotyped retrovirus that result from expression of these sequences is thus present, and would be clear to workers skilled in the art.

The Examiner also questioned the sufficiency of the detail provided regarding the arrangement of the nucleotide sequences on expression vectors. The Examiner is directed to page 17 line 4 to page 18, line 2, which describes various arrangements of the nucleotide sequences on expression vectors. Applicants have also provided new dependent claims 56 - 58 directed to several preferred arrangements. Applicants note, however, that workers skilled in the art realize that the nucleotide sequences can be delivered and function independently, or in any combination, relative to each other, and that exact arrangement of the sequences on the expression vectors does not significantly impinge on the structural/functional nexus of the invention, as described above.

On a related note, the Examiner stated that the transfected constructs may result in transient or stable expression of the proteins. Applicant replies that both transient and stable expression of retroviral particles are within the scope of the independent claims. Both types of expression are disclosed within the specification, and examples are provided that demonstrate how both types of expression may be accomplished (see, for example, Example 2 and Example 3 for transient and stable expression, respectively, using RRV). Inclusion of both types of expression does not render the claims vague and indefinite. Dependent claims to cells having chromosomally integrated nucleotide sequences are provided that are directed specifically to stable cell lines.

The Examiner further rejected claims 19-29 as vague and indefinite for being based on an "illogical" preamble. Applicants have amended claims 19, 26, and 53 to clarify that a cell is not formed; rather, a cell is modified to prepare a pseudotyped-retrovirus-producing cell. If these amendments have not obviated the rejection, Applicants respectfully request that the Examiner provide further clarification on how the preamble is illogical.

The Examiner also rejected claims 40-43 based on use of the phrase "selected ribonucleotide sequence" as vague and indefinite. Applicants have provided guidance as to the identity of selected nucleotide sequences in the specification; for example, on page 15, lines 17-26 or on page 21, line 15 to page 22, line 3. One example of a selected nucleotide sequence discussed in the specification is a sequence producing a marker protein. However, the precise identity and/or function of the selected nucleotide sequence is not crucial to the independent claims of the present application, as they simply refer to a particular nucleotide sequence that is being delivered by the pseudotyped retroviral vector. The claims are not intended to be limited to any particular nucleotide sequence, and there is nothing in the specification that would suggest that any one sequence is preferred over any other. This nucleotide sequence is essentially a passenger of the viral vector, and need not be characterized in any detail to satisfy § 112, second paragraph, as any sequence selected by the user of the invention may be delivered.

The 35 U.S.C. §112, First Paragraph, Rejection

The Examiner rejected claims 1-12, 19-29, 33-38, 40-43, and 53 under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, the Examiner has raised the issue whether adequate support is provided for the broadly claimed genus of RVVPs, producer cell lines, and methods of making said cell lines. This rejection is respectfully traversed.

Note that applicants are assuming the acronym RVVP represents retroviral vector particles, as applicant's specification does not make use of this term, and we would appreciate clarification if our assumption is in error.

The Examiner states that the written description requirement may be satisfied through the disclosure of function and minimal structure when there is a well-established correlation between structure and function. The structures of numerous Gag, Pro, and Pol encoding sequences are well known, and there is a well-established correlation between these structures and the formation of retroviruses. See, for example, Retroviruses, J.M. Coffin, S. H. Hughes, H.E. Varmus, eds., Ch. 1, which states:

> "All retroviruses contain three major coding domains with information for virion proteins: *gag*, which directs the synthesis of internal virion proteins that form the matrix, the capsid, and the nucleoprotein structures; *pol*, which contains the information for the reverse transcriptase and integrase enzymes; and *env*, from which are derived the surface and transmembrane components of the viral envelope protein. An additional, smaller, coding domain present in all retroviruses is *pro*, which encodes the virion protease."

Further, as noted on p. 10, lines 15-30 of the specification, a wide variety of retroviral nucleotide sequences may be used within the scope of the present invention, a number of which are specifically disclosed. The correlation between the structure (foreign viral envelope glycoproteins) and function (expanded host range of a pseudotyped virus) is also well-established, as evidenced by the well-established use of the term "pseudotyped virus" by those skilled in the art. See for example U.S. Patent 5,512,421, issued to Burns et al., provided by applicants in the earlier filed information disclosure statement. As the present application discloses a functional nexus in which the correlation between structure and function is well-established, the burden of providing detailed structural information is reduced. Applicants have, in fact, more than met this reduced burden by providing significant structural data, in the form of numerous examples and the nucleotide sequences encoding for three different viral envelope glycoproteins. Applicants have thus shown possession of the claimed invention.

Applicants acknowledge Examiner's statement that a skilled artisan would reasonably conclude that applicants were "in possession of a recombinant MoMLV expression system that was capable of producing RRV-pseudotyped RVVPs". However, limiting the invention to a single recombinant retroviral vector system (MoMLV) when a wide variety of retroviral vectors are known in the art, as disclosed in the present application, is not be necessary, particularly as applicants are not claiming such retroviral vectors, but rather simply using them as a means to prepare a retrovirus-producing cell. See, for example, page 11, first paragraph, for reference to retroviruses available from the American Type Culture Collection. The only retroviral vector being claimed is the actual pseudotyped retrovirus prepared by the modified eukaryotic cells (see claim 33 and its dependent claims). Furthermore, limiting the invention to Ross River Virus envelope glycoproteins is also unwarranted, as three envelope glycoprotein-encoding nucleotide sequences (Ross River, Ebola, and Marburg) have been specifically disclosed, and the suitability of a wide variety of other viral glycoproteins has also been disclosed. See for example page 12, lines 21 to page 13, line 10, which discloses the suitability of viral glycoproteins from Togaviridae, Paramycoviridae, and Buyaviridae. Given the requirement that the Examiner has the initial burden of presenting, by a preponderance of the evidence, why a person skilled in the art would not recognize in an applicant's disclosure a description of the invention defined by the claims (In re Wertheim, 541 F.2d 257, 263, 191 USPQ 90, 97 (CCPA 1976)), applicant requests that the rejection under 35 U.S.C. §112, first paragraph should be withdrawn in light of the amendments and the arguments provided above.

Summary

It is respectfully submitted that the pending claims 1-12, 19-23, 25-28, 33-38, 53, and 56-58 are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicants' Representatives, at the below-listed telephone number, if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted for
Purdue Research Foundation

By
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Nov 17, 2004
Date

By: Victoria A. Sandberg
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CERTIFICATE UNDER 37 CFR §1.8:
The undersigned hereby certifies that the Transmittal Letter and the paper(s), as described hereinabove, are being transmitted by facsimile in accordance with 37 CFR §1.6(d) to the Patent and Trademark Office, addressed to Mail Stop Amendment, Commissioner for Patents, Attn: Examiner Parkin, P.O. Box 1450, Alexandria, VA 22313-1450, on this 17 day of November, 2004, at 11:50 A.M. (Central Time).

By: Sandy Truehart
Name: Sandy Truehart

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PATENT
Docket No. 290.00490101

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Sanders et al.
Serial No.: 09/762,224
Confirmation No.: 2859
Filed: 30 July 2001
Group Art Unit: 1648
Examiner: Jeffrey S. PARKIN

For: PSEUDOTYPED RETROVIRUSES AND STABLE CELL LINES FOR THEIR PRODUCTION

FACSIMILE TRANSMISSION TO THE PTO

Mail Stop Amendment
Commissioner for Patents
Attn: Examiner Parkin
P.O. Box 1450
Alexandria, VA 22313-1450

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Mueting, Raasch & Gebhardt, P.A.
Customer Number: 26813

Nov 17, 2004
Date

By: Victoria A. Sandberg
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PATENT
Docket No. 290.00490101

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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Mueting, Raasch & Gebhardt, P.A.
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